

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NEWPORT NEWS DIVISION**

SOLSYS MEDICAL, LLC,

Plaintiff,

v.

ORGANOGENESIS, INC.,

Defendant.

Case No. 4:18-cv-00030-HCM-RJK

**DEFENDANT’S MEMORANDUM IN SUPPORT OF ITS
MOTION TO DISMISS PLAINTIFF’S COMPLAINT**

Scientific controversies must be settled by the methods of science rather than by the methods of litigation. More papers, more discussion, better data, and more satisfactory models—not larger awards of damages—mark the path toward superior understanding of the world around us.

Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994) (Easterbrook, J.)

Solsys does not like the Peer-Reviewed Study at the heart of this case.¹ That Study was published in a well-respected, independent journal and provided to health care professionals — a sophisticated medical audience consisting of physicians, Ph.D.s, and other specially trained health professionals skilled in the wound healing area. Rather than contest the findings and conclusions of the Study with more research, more discussion, better data, and more satisfactory models, however, Solsys seeks to employ methods of litigation to squelch its dissemination.

¹ “*Comparative Effectiveness of a Bioengineered Living Cellular Construct and Cryopreserved Cadaveric Skin Allograft for the Treatment of Venous Leg Ulcers in a Real-World Setting*,” published in the independent, peer-reviewed medical journal, *Advances in Wound Care*, Vol. 7, No. 3 (Dec. 2017) (hereinafter the “Peer-Reviewed Study” or “Study”). *Advances in Wound Care* is an official publication of the Wound Healing Society (“WHS”). The e-mail that distributed the Study is referred to as the “Cover E-Mail.”

Among the relief it seeks, Solsys wants this Court to compel a “retraction of any references to or any information regarding” the Peer-Reviewed Study — an unprecedented and unconstitutional prior restraint if ever there was one.

In launching an attack on the Peer-Reviewed Study, the Complaint strikes at the heart of the First Amendment. It seeks to silence a crucial conversation among scientific and medical professionals concerning the optimal treatment of venous leg ulcers (“VLUs”) — a debilitating medical condition and a matter of urgent public health interest. But the importance of fostering robust discussion of scientific ideas and discoveries is exactly why the First Amendment protects the content of the Peer-Reviewed Study, as well as the Cover E-Mail, which does nothing more than restate the scientific and medical conclusions of the Peer-Reviewed Study included with and incorporated into it.

As Judge Easterbrook observed, scientific disagreements should not, and cannot, be settled by the courts. Solsys must pursue its dissent in the academic and scientific communities, not here. Accordingly, the Court should dismiss this case forthwith.

FACTUAL BACKGROUND

On December 22, 2017, the independent medical journal *Advances in Wound Care* published the Peer-Reviewed Study.² Following its publication online, Organogenesis transmitted the Study via the Cover E-Mail to wound care professionals to bring to their attention important new information about available medical therapies for treating VLUs.

Advances in Wound Care is a publication of the Wound Healing Society (“WHS”), a well-respected scientific organization dedicated to “improv[ing] wound healing outcomes through science, professional education, and communication.” The journal is considered an

² <https://www.liebertpub.com/doi/abs/10.1089/wound.2017.0738>

authoritative desktop reference for wound care professionals³ and provides a critical forum for the field of tissue injury and repair, with an emphasis on acute and chronic wound care to optimize patient outcomes. The Peer-Reviewed Study compared wound healing outcomes for Organogenesis's product, Apligraf, and Solsys's product, TheraSkin, based on an analysis of data obtained from a wound care-specific database of Electronic Medical Records ("EMR"). *See* Compl. Ex. 1 at 75. The entity that gathered the data on which the study is based, Net Health, is entirely independent of Organogenesis. *See* <https://www.nethealth.com/company>. Because this database is utilized by approximately 90% of wound care facilities across the United States, it allowed for the inclusion of a large, geographically diverse patient population. *See* Compl. Ex. 1 at 75.

Solsys objects to the publication of the Study as well as to Organogenesis's dissemination of the Study with a Cover E-Mail that "includes and incorporates" a link to the Study and succinctly restated the Study's findings. As explained below, the nature of Solsys's objections makes readily apparent that its real objective is to stifle legitimate scientific discourse that it believes undercuts its economic position. This it cannot be permitted to do. Solsys may not "simply by filing suit and crying 'character assassination!'", silence those who hold divergent

³ *See* <http://woundheal.org/Publications/Advances-in-Wound-Care.cgi> and <http://woundheal.org/About/>. Founded in 1989, the WHS is the premier scientific organization focused on wound healing. A nonprofit organization composed of clinical physicians, scientists, and wound care specialists, the mission of the WHS is to improve wound healing outcomes through science, professional education, and communication. The WHS provides a forum for interaction among scientists, clinicians, and other wound care practitioners, industrial representatives, and government agencies. *Advances in Wound Care* is an official publication of the WHS. Judicial notice and consideration of information published on WHS's and the journal's website is appropriate for the Court pursuant to Federal Rule of Evidence 201. *In re BearingPoint, Inc. Sec. Litig.*, 232 F.R.D. 534, 540 n.9 (E.D. Va. 2006). The journal is published by Mary Ann Liebert, Inc. under the editorial leadership of Editor-in-Chief Chandan K. Sen, Ph.D.

views, no matter how adverse those views may be to [its] interests.” *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994).

ARGUMENT

I. The Solsys Complaint Fails to State a Cause of Action Under the Federal Lanham Act.

A. The Creation, Publication and Dissemination of the Peer-Reviewed Study Is Protected by the First Amendment and Does Not Violate the Lanham Act.

The Lanham Act generally prohibits the use in advertising of any “false or misleading description of fact, or false or misleading representation of fact.” 15 U.S.C. § 1125(a)(1). Representations that are not “commercial speech” do not give rise to Lanham Act liability, *Tao of Sys. Integration, Inc. v. Analytical Servs. & Materials, Inc.*, 299 F. Supp. 2d 565, 572 (E.D. Va. 2004), nor do representations that merely constitute a speaker’s opinion. *Design Res., Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 502 (4th Cir. 2015). In determining whether an academic work is advertising containing actionable statements of fact under the Lanham Act, courts tread carefully because academic freedom is “a special concern of the First Amendment.” *See, e.g., Keyishian v. Bd. of Regents of the Univ. of the State of N.Y.*, 385 U.S. 589, 603 (1967). Solsys’s Complaint presents precisely such a case. Because the gravamen of the Complaint is an attack on a peer-reviewed academic publication, its allegations strongly implicate the First Amendment, which vouchsafes to the public “access to discussion, debate, and the dissemination of information and ideas.” *First Nat’l Bank of Boston v. Bellotti*, 435 U.S. 765, 783 (1978); *see also Rossignol v. Voorhaar*, 316 F.3d 516, 522 (4th Cir. 2003) (“The First Amendment . . . protects both a speaker’s right to communicate information and ideas to a broad audience and the intended recipients’ right to receive that information and those ideas.”).

The Second Circuit considered precisely the circumstances at issue here in *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013). In *ONY*, as here, the plaintiff

alleged that a scientific article concerning competing therapeutic products, which had been published in a peer-reviewed academic journal, constituted false advertising because it “made statements about scientific findings that were intentionally deceptive and misleading.” *Id.* at 496. The reasoning of the Second Circuit in upholding the dismissal of that case is persuasive and directly applicable here.

The *ONY* court began with the recognition that, in general, “it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation.” *Id.* For this reason, “while statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable ‘fact,’ for purposes of the First Amendment . . . they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities.” *Id.* at 497. Accordingly, the court concluded that conclusions published in a peer-reviewed journal article that were drawn “from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement . . . *are not grounds for a claim of false advertising under the Lanham Act.*” *Id.* at 498 (emphasis added). In so holding, the Second Circuit noted that courts are, “[n]eedless to say, . . . ill-equipped to undertake to referee [scientific] controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.”⁴ *Id.* at 497.

⁴ Whether a statement is nonactionable opinion or an assertion of actionable fact is a threshold question of law to be resolved on a motion to dismiss. *Steinhilber v. Alphonse*, 501 N.E.2d 901, 904 (N.Y. 1986) (the question “whether a given statement expresses fact or opinion

In *ONY*, the Second Circuit relied in part on the decisions of other courts declining to allow suits based on claims of false conclusions in matters of scientific controversy to proceed. In particular, the *ONY* court referred to Judge Easterbrook's decision in *Underwager*, quoted at the outset of this Memorandum. *Id.* The *ONY* court also noted that district courts, including this Court, have similarly declined to find controversial questions of medical science actionable. *See id.* (citing *Arthur v. Offit*, No. 01:09-cv-1398, 2010 WL 883745, at *6 (E.D. Va. Mar. 10, 2010) (finding that "Plaintiff's claim . . . threatens to ensnare the Court in [a] thorny and extremely contentious debate over . . . which side of this debate has 'truth' on their side. That is hardly the sort of issue that would be subject to verification based upon a core of objective evidence." (internal quotation marks omitted))); *see also Oxycal Labs., Inc. v. Jeffers*, 909 F. Supp. 719, 724 (S.D. Cal. 1995) ("The Court cannot inquir[e] into the validity of ... scientific theories, nor should it.").

Unlike *Mimedx Group, Inc. v. Osiris Therapeutics, Inc.*, No. 16 Civ. 3645 (KPF), 2017 WL 3129799 (S.D.N.Y. July 21, 2017), Solsys directly attacks the Peer-Reviewed Study and seeks to have the Court prohibit Organogenesis from discussing or even distributing it. In *Mimedx*, the plaintiff originally attacked the study before it was published in a peer-reviewed journal. However, once the study was accepted and published, the plaintiff amended its complaint and conceded that "Plaintiff has no quarrel with the Study, be it methodology, conclusions, or otherwise." *Id.* at *7. In stark contrast to *Mimedx*, here, Solsys's quarrel is precisely with the manner in which the Peer-Reviewed Study was carried out. It is attempting to use the Lanham Act as a bludgeon to suppress the dissemination of scientific ideas and

. . . is one of law for the court"); *Raytheon Tech. Servs. Co. v. Hyland*, 641 S.E.2d 84, 91 (Va. 2007) ("whether a statement is a statement of fact or opinion is an issue of law").

conclusions that it disagrees with or finds inconvenient. However, as described above, the relevant case law makes clear that a mere scientific disagreement does not turn an academic publication into false advertising within the purview of the Lanham Act. The First Amendment protects the publication and dissemination of the Peer-Reviewed Study. Thus, there can be no liability under the Lanham Act.

B. Dissemination of the Cover E-Mail Is Also Protected by the First Amendment Because the E-Mail Does Nothing More than Restate the Content of the Study Without Distortion.

Because the Cover E-Mail transmitting the Peer-Reviewed Study to health care professionals does nothing more than, without distortion, report the Study's findings, the Cover E-Mail itself also cannot ground a claim under the Lanham Act.

The Complaint contains no non-conclusory allegation that the Cover E-Mail distorts or misrepresents the content of the Peer-Reviewed Study (which, as discussed above, is non-commercial and non-actionable speech fully protected by the First Amendment), or that it contains additional false or misleading commercial representations alongside accurate restatements of a journal article's content. (Solsys can hardly allege that the Cover E-Mail distorts or misrepresents the findings of the Study when it acknowledges in the Complaint that the Cover E-Mail "includes and incorporates" a complete linked copy of the Peer-Reviewed Study. *See* Compl. ¶ 31. The closest Solsys gets to such an allegation is that "[u]pon information and belief, Organogenesis' Retrospective Study included numerous errors and omissions that call into question both the validity of the study's conclusions and the objectivity of its authors." Compl. ¶ 25. This is nothing less than an attack on the Peer-Reviewed Study itself, and thus fails on the same First Amendment grounds discussed above. True and consistent as it was to the content of the Study being transmitted, the dissemination of the Cover E-Mail can no more form the basis of a Lanham Act violation than the dissemination of the Study itself. As the Second

Circuit held in *ONY*, “the secondary distribution of excerpts of [a scientific] article cannot give rise to liability, so long as the excerpts do not mislead a reader about the conclusions of the article.”⁵ *ONY*, 720 F.3d at 492.

It is apparent that Solsys’s real objection to the Cover E-Mail is simply that it restates the findings of a scientifically compelling study that showed that Apligraf outperforms TheraSkin in healing chronic VLU, a matter of intense concern to the wound care professionals who were the recipients of the Cover E-Mail. For this reason, Solsys’s objections to the Cover E-Mail impinge on the very heart of First Amendment values. When litigation threatens to curtail speech that relates to an issue of public concern, “the constitutional and common law protections—under both Commonwealth and federal law—here are at their zenith.” *Offit*, 2010 WL 883745, at *4. Permitting a competitor to enjoin and silence academic discussion of scientific literature by charging that the discussion violates the Lanham Act impermissibly intrudes on core First Amendment values and protections. *ONY*, 720 F.3d at 492, 498; *Wellnx Life Scis. Inc. v. Iovate Health Scis. Research Inc.*, 516 F. Supp. 2d 270, 287 (S.D.N.Y. 2007) (dismissing false advertising claim where defendant had truthfully communicated its rates, schedules, and specifications). It would also, to the detriment of American health care, create a significant disincentive for companies to carry out research on comparative outcomes of marketed products. There would, after all, be no reason to invest the substantial resources required to carry out the type of rigorous study that can withstand the peer-review process if the study could not then be

⁵ The *Mimedx* case does not demand a different conclusion. In *Mimedx*, the plaintiff challenged two promotional pieces — a brochure and a press release. Only the press release was related to the publication of a peer-reviewed study in a scientific journal. The court dismissed one of the press release claims on motion and held that the other survived “if only barely.” 2017 WL 3129799, at *11. In particular, the challenged claim in the press release went beyond the content of the published article and did not incorporate or accompany a copy of the article itself.

publicly discussed with healthcare providers for fear of having to defend a Lanham Act suit. The Supreme Court expressed this precise concern in *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 279 (1964) (saying that, in the absence of First Amendment protection, potential participants in academic debate “may be deterred from voicing their [opinion], even though it is believed to be true and even though it is in fact true, because of doubt whether it can be proved in court or fear of the expense of having to do so”).

C. Solsys Has Not Pleaded Facts That Support a Cause of Action for False Advertising Under the Lanham Act.

Putting aside the First Amendment objections to the allegations in the Complaint, Solsys’s allegations with respect to the Cover E-Mail fail to state an actionable claim for false advertising under the Lanham Act, which requires (in relevant part) that a defendant made a false or misleading description or representation *of fact* in a commercial advertisement which actually deceives or has the tendency to deceive a substantial segment *of its audience*. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002). Solsys has not pleaded facts to establish these elements of the cause of action. First, as discussed above, there are no allegations that Organogenesis disseminated any false or misleading statements of *fact* (as opposed to simply restating non-actionable statements of *scientific opinion*). Second, there are no factual allegations that the Cover E-Mail (or the Peer-Reviewed Study incorporated into the Cover E-Mail) deceived or had a tendency to deceive a substantial segment of the intended audience of health care professionals who received it. Indeed, the Peer-Reviewed Study clearly and thoroughly disclosed the study methodology and limitations, including a discussion of the factors that were considered to control for potentially confounding variables. *See* Compl. Ex. 1 at 74-75. Even if Solsys is correct that reliable conclusions cannot be reached without including other data, the intended audience of the Peer-Reviewed Study and Cover E-Mail — physicians and other

clinicians and scientists in the field of wound care — are (to borrow a phrase from product liability law) “learned intermediaries” who are sophisticated enough to read the article and understand the study design, methods, data, and self-reported limitations presented in the article and evaluate independently the validity and credibility of the authors’ findings and opinions.

The context of the Cover E-Mail and its intended audience matter. *Plough, Inc. v. Johnson & Johnson Baby Prods. Co.*, 532 F. Supp. 714, 717 (D. Del. 1982) (“Context can often be important in discerning the message conveyed and this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience”). “Hence, a target audience’s special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product.” *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990). Organogenesis’s Cover E-Mail is directed at health care professionals who are, by virtue of their training and professional experience, accustomed to the nuances of medical science debates presented in peer-reviewed journals. Solsys entirely fails to plead any facts to support the required element of a false advertising claim that any physicians or other medical providers working in hospitals or wound care centers (much less a substantial portion of that intended audience) were, or reasonably might have been, misled by the Peer-Reviewed Study or the Cover E-Mail incorporating a link to the Study. The Complaint’s rote recitation that Organogenesis’s “statements actually deceive, or have a tendency to deceive, a substantial segment of customers and potential customers of wound care products,” (Compl. ¶ 50), is nothing more than a “naked assertion” devoid of “further factual enhancement.” It cannot survive a motion to dismiss. *See Bell Atl. Corp. v.*

Twombly, 550 U.S. 544, 557 (2007).⁶ Failure to plead facts that establish the manner in which the Cover E-Mail deceived or had the tendency to deceive a substantial portion of the intended audience is in itself grounds for dismissal of Solsys's false advertising claim. *See Ameritox, Ltd. v. Millennium Labs., Inc.*, No. 8:11-cv-775-T-24-TBM, 2012 WL 33155, at * 3 (M.D. Fla. Jan. 6, 2012) (dismissing false advertising claim for failure to plead that advertisements actually deceived customers or had the tendency to deceive a substantial portion of the targeted audience).

D. The Cover E-Mail, on its Face and as a Matter of Law, Is Neither False Nor Misleading.

Finally, on its face and as a matter of law, there is nothing false or misleading about the Cover E-Mail. As Exhibit 1 of its Complaint, Solsys provides a copy of the Cover E-Mail, which makes the following statements that Solsys challenges as "false advertising":

- "Apligraf® Does It Again!"
- "Similar to Apligraf's VLU pivotal trial, APLIGRAF CLOSES MORE VLUs, FASTER IN A COMPARATIVE EFFECTIVENESS STUDY."
- "Apligraf Closes More VLUs, Faster Compared to Theraskin."

The Court's plain reading of the Cover E-Mail will confirm that it simply restates the principal conclusions of a peer-reviewed journal article accurately and without distortion. *See* Compl. Ex. 1. Accordingly, even viewed in the light most favorable to Solsys, these statements

⁶ Indeed, this failure goes beyond just a pleading defect. Courts have recognized that "a proffered hypothesis that is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture." *Gross v. N.Y. Times Co.*, 623 N.E.2d 1163, 1168 (N.Y. 1993) (citing *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 28 n.5 (1990) (Brennan, J. dissenting)). Statements that are fully explained and qualified like those in the Peer-Reviewed Study and the Cover E-Mail signal to "readers or listeners that what is being read or heard is likely to be opinion, not fact." *Id.* (quoting *Steinilber*, 501 N.E.2d at 554). Where, as here, an advertiser's description of the conclusions in the underlying work of opinion are accurate, there is no claim under the Lanham Act. *Groden v. Random House, Inc.*, 61 F.3d 1045, 1051 (2d Cir. 1995); *ONY*, 720 F.3d at 498.

are literally true and, furthermore, cannot reasonably be viewed as misleading to the intended audience. Any reasonable health care provider could only read these statements as conveying that Organogenesis sponsored a comparative effectiveness study of Apligraf and TheraSkin in patients with VLU, and that the results of the study showed that Apligraf was more effective than TheraSkin. Thus, Apligraf “again” was the better wound care treatment, just as it had been in its earlier Pivotal Trial described generally in paragraphs 9-14 of the Complaint.

Solsys’s assertion that Organogenesis offers its “own interpretation” of the Peer-Reviewed Study in the Cover E-Mail, *see* Compl. ¶ 30, is nothing more than a “naked assertion” that does not state a plausible claim under the Lanham Act — especially when the Peer-Reviewed Study is incorporated into the Cover E-Mail. *See ONY*, 720 F.3d at 492, 498. Solsys offers no further guidance as to where such interpretive statements appear in the Cover E-Mail, nor does Solsys allege that any such interpretative statement in any way distorts the study’s findings. Solsys’s argument — that “[b]y linking Organogenesis’s Pivotal Trial with Organogenesis’s Retrospective Study, Organogenesis is intentionally deceiving the consumer into believing that Organogenesis’s Retrospective Study incorporated the same protocols, and received the same FDA stamp of approval,” Compl. ¶ 36 — is facially absurd and need not be credited by the court.⁷ Nothing in the Cover E-Mail or the linked Peer-Reviewed Study that the

⁷ When considering a motion to dismiss for failure to state a claim, a plaintiff’s well-pleaded allegations are taken as true and the complaint is viewed in the light most favorable to the plaintiff. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). This principle applies only to factual allegations, however, and “a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). In other words, “labels and conclusions” or a “formulaic recitation of the elements of a cause of action” will not suffice. *Id.* at 678 (citations omitted). Instead, a plaintiff must assert facts that rise above speculation and conceivability to those that “show” a claim that is “plausible on its face.” *Id.* at 678–79 (citing *Twombly*, 550 U.S. at 570).

Cover E-Mail summarizes in any way suggests that the identical methodology was used in both trials, or that the Retrospective Study was the subject of FDA review and approval. No reasonable health care provider could possibly understand the Cover E-Mail in the manner described by Solsys, and there are no factual allegations to support this conclusory and bizarre contention, which in any event is flatly contradicted by a plain reading of Exhibit 1.

Instead, the Cover E-Mail reports truthfully that, *in the Peer-Reviewed Study*, Apligraf closed 18% more VLUs than TheraSkin by week 12, Apligraf closed 24% more VLUs than TheraSkin by week 24, and Apligraf closed VLUs 52% faster than TheraSkin. Compl. Ex. 1. Again, these statements are literally true and reflect the actual data presented in the study. There is no ambiguity about these factually accurate statements. Solsys provides no good-faith explanation as to how accurate reporting of test results can be deemed “false or misleading” or otherwise actionable under the Lanham Act.

II. Neither the Creation, Publication and Dissemination of the Study, Nor the Dissemination of the Cover E-Mail, Violates Section 18.2-216 of the Virginia Code.

Virginia false advertising law is more restrictive than the Lanham Act because the Virginia law is a penal statute, which must be strictly construed. Virginia Code Section 18.2–216 prohibits the use, in any advertisement, of “any promise, assertion, representation or statement of fact which is untrue, deceptive or misleading” if the advertisement is made with the “intent to sell” or “to induce the public” to enter into an obligation. *Henry v. R.K. Chevrolet, Inc.*, 219 Va. 1011, 1013, 254 S.E.2d 66, 67 (Va. 1979). Section 18.2–216 also “subjects the defendant to an action for damages [under Va. Code Ann. § 59.1–68.3] by any person who suffers loss as the result” of a statutory violation. *Id.*; *see also Klaiber v. Freemason Assocs., Inc.*, 266 Va. 478, 587 S.E.2d 555, 559 (2003) (“[Section 59.1–68.3] by its express terms requires, however, that the plaintiff must ‘suffer loss’ in order to recover damages.”).

As a “penal statute,” Section 18.2–216 “must be construed strictly” and should not “be extended by implication, or be made to embrace cases which are not within its letter and spirit.” *Henry*, 219 Va. at 1014, 254 S.E.2d at 68 (internal quotation marks omitted); *Persaud Cos. v. IBCS Grp., Inc.*, 425 F. App’x 223, 227 (4th Cir. 2011) (finding summary judgment for plaintiff improper where there was no evidence of loss due to the advertisement).

Because the Virginia statute prohibiting false advertising is more narrowly construed than the Lanham Act, Solsys’s second cause of action under Virginia Code Section 18.2–216 fails for all the reasons discussed above. In addition, Solsys has not pleaded any non-conclusory factual allegations that it has suffered any actual loss due at least in part to the accused conduct. Because Solsys’s naked assertion that it “has been injured and is likely to be further damaged by these continuing violations of § 18.2–216” (Compl. ¶ 61) is wholly lacking in factual support, this claim should be dismissed for failure to state a plausible cause of action. *Iqbal*, 556 U.S. at 678, *Twombly*, 550 U.S. at 570. Solsys’s request for injunctive relief under this claim must also be dismissed outright because injunctive relief is not a recognized remedy for a private action for false advertising under Virginia law. *See Physicians Comm. for Responsible Med. v. Gen. Mills, Inc.*, 283 F. App’x 139, 142 (4th Cir. 2008) (holding that there is no private false advertising cause of action for injunctive relief).

III. The Injunctive Relief Solsys Seeks Is Contrary to Established Constitutional Principles.

The grossest overreach in Solsys’s Complaint is its request for injunctive relief that “includes but is not limited to removal of all false or misleading advertisements and corrective advertising to remedy the effects of Organogenesis’s false advertising, including but not limited to the [E-Mail]” and “[f]or an order requiring Organogenesis to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of Apligraf

including without limitation the placement of corrective advertising and providing written notice to the public *and a retraction of any references to or any information regarding Organogenesis's Retrospective Study.*" Compl. Prayer for Relief ¶¶ 1-2 (emphasis added). Solsys's prayer for relief is not only technically impossible (Organogenesis has no authority to retract an article published in a scholarly journal that it does not control), but the First Amendment flatly prohibits it. The sweeping request for injunctive relief also underscores that this lawsuit is nothing more than a transparent effort to intimidate researchers and restrict protected speech.

The contribution of scientific opinion to a public debate over patient health and safety in the treatment of VLUs unquestionably receives strong First Amendment protection. That the speech at issue raises reasonable questions about, or even criticizes, Solsys's commercial product does nothing to take it outside the First Amendment's shield. *See generally, e.g., Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 504 (1984) ("Under our Constitution 'there is no such thing as a false idea. However pernicious an opinion may seem, we depend for its correction not on the conscience of judges and juries but on the competition of other ideas.'") (citation omitted). Asserting a false advertising claim does not change this analysis. Solsys's claims are based on the publication of a scientific paper protected by the First Amendment. Absent non-conclusory allegations that secondary advertising or promotion of that study misstated or distorted the results of that study, there is no legal predicate for any claim or for any relief. *See ONY*, 720 F.3d at 498.

Injunctions against speech are strongly disfavored, reflecting a "deep-seated American hostility to prior restraints." *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 589 (1976) (Brennan, J., concurring). Such restraints are extremely rare, even in cases that focus on commercial interests. "No prior decisions support the claim that the interest of an individual in being free from public

criticism of his business practices . . . warrants use of the injunctive power of a court.” *Org. for a Better Austin v. Keefe*, 402 U.S. 415, 419 (1971).

Judicially compelled speech is even more repugnant to constitutional principles. Solsys’s demand for a compulsory retraction and corrective advertising (which is tantamount to a compelled confession of scientific wrongdoing) has no support in the law. The Supreme Court has rejected efforts to force the publication of any content, holding that “any such compulsion to publish that which reason tells them should not be published is unconstitutional.” *Miami Herald Publ’g Co. v. Tornillo*, 418 U.S. 241, 256 (1974) (internal quotation marks omitted); *see also DeBoer v. Vill. of Oak Park*, 267 F.3d 558, 572 (7th Cir. 2001) (the government cannot “force a speaker to tailor its speech to an opponent’s agenda or respond to an opponent’s arguments when it might prefer to be silent.”) The Third Circuit has observed that, “[a]lthough the notion of compelled retraction occasionally has been advanced in the literature, we have not found a single case in which such a remedy has been awarded.” *Kramer v. Thompson*, 947 F.2d 666, 680 (3d Cir. 1991). Solsys’s overbroad and unconstitutional demands for injunctive relief should be firmly rejected.

CONCLUSION

As the Second Circuit wisely observed in the *ONY* case, the “trial of ideas” should play out “in the pages of peer-reviewed journals” rather than in a courtroom. 720 F.3d at 497. Solsys has academic and scientific remedies available to it. Yet, Solsys has brought its scientific disagreements into this Court to subject them to the methods of litigation. Those quarrels do not belong here — that is the essence of the First Amendment. Accordingly, Solsys’s claims should be dismissed in their entirety and with prejudice for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6).

Dated: May 10, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filings (NEF) and paper copies of the document will be sent to those indicated as non-registered participants.

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